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Outcome of assessment on use of Neuraceq to monitor treatment response

The European Medicines Agency has finalised its assessment of an application to extend the use of Neuraceq in adults to monitor their response to treatments that reduce beta amyloid plaques. These plaques are abnormal clumps of protein that build up in the brain of people with Alzheimer's disease, leading to problems with brain function.

Although EMA did not recommend this use, it agreed that the medicine's product information should be updated so that healthcare professionals have access to up-to-date information.

What is Neuraceq and what is it used for?

Neuraceq is a diagnostic medicine used with a type of brain scan called positron emission tomography (PET) to check for the presence of beta amyloid plaques in the brain.

Neuraceq is used with a PET scan in adults with cognitive impairment (problems affecting the memory or ability to think) who are being evaluated for Alzheimer's disease and other diseases that cause cognitive impairment. A negative scan indicates few or no beta amyloid plaques, meaning a patient is unlikely to have Alzheimer's disease. Doctors use the results of these scans along with a clinical evaluation to make a diagnosis as a positive scan on its own is not sufficient.

Neuraceq contains the active substance florbetaben (^{18}F) and is available as a solution for injection. It has been authorised in the EU since February 2014.

Further information on Neuraceq's current uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/neuraceq

What change had the company applied for?

The company applied to extend the use of Neuraceq in adults to monitor their response to treatments to reduce beta amyloid plaques.

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How does Neuraceq work?

The active substance in Neuraceq, florbetaben (^{18}F), is a radiopharmaceutical that emits low amounts of radiation. It works by targeting and attaching to beta amyloid plaques in the brain. When florbetaben (^{18}F) attaches to these plaques, the radiation it emits is seen on a PET scan, allowing doctors to determine if significant amounts of plaques are present.

What did the company present to support its application?

The company presented data from studies in the medical literature in which PET scans were used to monitor the response to treatments intended to reduce beta amyloid plaques.

What were EMA's conclusions?

EMA considered that the data provided by the company did not support the change in use of Neuraceq. The Agency concluded that a study is needed to evaluate how well Neuraceq PET scans perform when used to monitor treatment response. They also considered that the company should provide data regarding the method for interpreting Neuraceq PET scans including validation (formal test to check suitability) of the method.

Although Neuraceq will therefore not be authorised to monitor treatment response, the prescribing information for Neuraceq will be updated, so that healthcare professionals have access to up-to-date information.

Does this outcome affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Neuraceq.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.